

REMARKS

This Amendment is submitted in response to an Office Action dated May 21, 2003. In the Office Action, the Patent Office objected to Claims 1-26 for informalities. More specifically, the Patent Office objected to independent Claims 1, 7 and 15 because it is unclear if Applicant is claiming the catheter introducer, the catheter assembly or the catheter itself. Further, the Patent Office is under the impression that Applicant is claiming the catheter assembly and requests that the preamble read as such. Moreover, the Patent Office rejected Claims 1-14 and 21-26 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,059,802 to Ginn in view of U.S. Patent No. 5,360,414 to Yarger.

Applicant notes with appreciation that the Patent Office indicated that Claims 15-20 are in allowable form.

By the present Amendment, Applicant amended Claims 1-11 and 21-26. Applicant amended Claims 1-11 and 21-24 to clarify that the catheter assembly is the claimed invention. Additionally, Applicant amended Claims 25 and 26 to have proper antecedent basis from the method Claim 15. Further, Applicant submits that Claims 25 and 26 are allowable since Claim 15 is allowable. Applicant submits that the amendments to the claims and the reasons that follow place the application in condition for allowance. Further, Applicant submits that independent Claim 15 is claiming a method for introducing a catheter into a body of a patient. Therefore, the preamble of Claim 15 was not amended.

With respect to the rejection of Claims 1-14 and 21-26 under 35 U.S.C. §103(a) as being unpatentable over Ginn in view of Yarger, Applicant submits that this rejection has been overcome in view of the amended claims and for the reasons that follow.

More specifically, the Patent Office alleges:

**DRAFT** Ginn teaches a catheter introducer device comprising of a cylindrical body defining a cross with a length defined between a pointed end and a flat end. A first part and a second part, wherein the first and the second part defines the cylindrical body. Locking mechanism (figs 6-7) where the first part and the removable second part are locked together. The pointed end of the cylindrical body gradually tapers to the cylindrical portions. A recess portion along the length of the first portion and a protruding element defined in shape by a right angle located along the recessed portion of the first part. The recess portion may readily accept the protrusion along the length of the removable second part. A first hole located a distance from the pointed end of the cylinder. A leg attached to the bottom end of the cylinder. A second hole located on the leg of the cylinder and a thread connected (locking mechanism) to the cylinder form the second hole to the first hole. A groove or plurality of holes cut into the cylinder. Ginn does not teach a catheter with two notches located a distance from each other. **DRAFT**

The Patent Office alleges that Yarger teaches a catheter (tube) with two notches which are located a distance from each other and have a locking mechanism located on the bottom end of the flexible body. Additionally, the Patent Office alleges that the tube has multiple holes. Moreover, the Patent Office alleges that it would have been obvious to one having ordinary skill in the art to have used the catheter introducer of Ginn for the introduction of a catheter or tube such as Yarger, because it is well known in the art that any tube or catheter **DRAFT**

needs an introducer for guidance and maneuvering into the body.

However, amended Claim 1 of the present invention defines a catheter assembly for placing within a body which has a locking mechanism located on the bottom end of the flexible body. Moreover, Claim 1 defines a top end of the flexible hollow body which is removably attached to the second part of the cylindrical body.

Further, amended Claim 7 of the present invention defines a catheter assembly for placing within a body. The catheter assembly further has a cylinder having a length defined between a pointed end and a second end wherein the top end of the flexible hollow body is removably attached to the pointed end of the cylinder. Further, Claim 7 defines a catheter assembly having a first hole located a distance from the pointed end of the cylinder, a leg attached to the bottom end of the cylinder and a second hole located on the leg of the cylinder. Moreover, Claim 7 requires a thread connected to the cylinder from the second hole to the first hole.

Additionally, Claim 12 of the present invention defines a catheter for infusing a local anesthetic. The catheter requires a flexible hollow body defining a length between a pointed end and a bottom end wherein the pointed end is closed and wherein the pointed end tapers to a cylindrical tube. Moreover, Claim 12 requires a locking mechanism located on the bottom end of the flexible body.

Contrary to the assertions of the Patent Office, Ginn merely teaches a slat assembly for harvesting vascular conduits or vessels. The slat assembly taught by Ginn requires two arcuate slats which are laterally translatable relative to each other. The two slats have similar cross-sections across their width

dimensions. To enable the lateral translation of the assembly, a series of slots is formed in one of the slats, and a corresponding series of pins is secured to the other slat with each pin being slidably contained by a corresponding slot. Moreover, Ginn teaches a corresponding series of pins having heads of a selected type and diameter and are molded, screwed into, or otherwise securely fastened to the lower slat. (See Ginn, col. 6, lines 13-16.) Furthermore, Ginn teaches "to vary the width dimension of the slide assembly, the upper slat is provided with a series of spaced, identical slots which, in this embodiment, extend diagonally at a selected angle across a major portion of the slat's width." (See Ginn, col. 6, lines 5-8.)

Furthermore, Yarger merely teaches a suction tube for removing fluid from a body cavity, viscus or wound. The tube has an elongate tubular section with an exterior surface and an interior surface defining an internal longitudinal passageway. The tube has a proximal end portion designed to be connected to a suction source and a distal end portion designed to be inserted into a body cavity, viscus or wound. The tubular section includes a plurality of radially extending, circumferentially spaced elongated portions extending along the length of the tubular section. Further, Yarger merely teaches a plurality of spaced holes extend transversely through the tubular body coupling the region surrounding the tubular body with the internal longitudinal passageway, wherein each of the transverse holes intersects more than one of the entrance channels and lumens. Moreover, Yarger teaches the connector has a counterbore for snugly receiving the proximal end portion of the tubular section and the bottom of the counterbore defines

an abutment shoulder against which the proximal end of the tubular section abuts. (See Yarger, col. 6, lines 20-26.)

~~DRAFT~~ Claim 12 neither Ginn nor Yarger, taken singly or in combination, teach or suggest a catheter assembly for placing within a body having a locking mechanism located on the bottom end of the flexible body as required by Claims 1, 7 and 12. Further, neither Ginn nor Yarger, taken singly or in combination, teach or suggest a catheter assembly for placing within a body having the top end of the flexible hollow body which is removably attached to the second part of the cylindrical body as required by Claims 1 and 7.

Additionally, neither Ginn nor Yarger, taken singly or in combination, teach or suggest a catheter assembly for placing within the body having a first hole located a distance from the pointed end of the cylinder and a second hole located on the leg of the cylinder as required by Claim 7. Furthermore, neither Ginn nor Yarger, taken singly or in combination, teach or suggest a catheter assembly for placing within the body having a thread connected to the cylinder from the second hole to the first hole as required by Claim 7. ~~DRAFT~~

Moreover, Ginn actually teaches away from the catheter assembly having a locking mechanism located on the bottom end of the flexible body as defined in the claims of the present invention because the series of slots are formed in one of the slats and a corresponding series of pins are secured to the other slat. The locking mechanism specifically defined in Claims 1, ~~DRAFT~~ 12 is located on the bottom end of the flexible body. Additionally, Ginn teaches away from the flexible hollow body which is removably attached to the second part of the cylindrical body as defined in the claims of the present

invention because the corresponding series of pins are molded, screwed into, or securely fastened to the lower slat. Moreover, Ginn teaches away from the flexible hollow body which is removably attached because the slat assembly only provides to vary the width dimension of the slide assembly. The flexible hollow body specifically defined in Claims 1 and 7 is removable attached to the second part of the cylindrical body. Thus, Ginn clearly teaches away from the catheter assembly having a locking mechanism located on the bottom end of the flexible body and the flexible hollow body which is removably attached to the second part as defined in the claims of the present invention.

Moreover, a person of ordinary skill in the art would never have been motivated to combine Ginn and Yarger in the manner suggested by the Patent Office in formula ~~the rejection~~ under 35 U.S.C. §103(a). More specifically, Applicant submits that the Patent Office is merely "piece-mealing" references together, providing various teachings and positively defined limitations of Applicant's catheter assembly to deprecate the claimed invention. Of course, hindsight reconstruction of Applicant's invention is impermissible. Applicant respectfully submits that Claims 1, 7 and 12 distinctly define the present invention from Ginn and Yarger, taken singly or in combination.

It is submitted that the question under §103 is whether the totality of the art would collectively suggest the claimed invention to one of ordinary skill in this art. In re Simon, 461 F.2d 1387, 17 ~~114~~ (CCPA 1972).

That elements, even distinguishing elements, are disclosed in the art is alone insufficient. It is common to find elements somewhere in the art. Moreover, most if not all elements perform their ordained and expected functions. The test is

whether the invention as a whole, in light of all of the teachings of the references in their entireties, would have been obvious to one of ordinary skill in the art at the time the invention was made. Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983).

It is insufficient that the art disclosed components of Applicant's invention, either separately or used in other combinations. A teaching, suggestion, or incentive must exist to make the combination made by Applicant. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1988).

In view of the foregoing remarks and amendments, Applicant respectfully submits the rejection of Claims 1-14 and 21-26 under 35 U.S.C. §103(a) has been overcome and should be withdrawn. Notice to that effect is requested.

Further, Claims 2-6, 21 and 22 depend from Claim 1; Claims 8-14, 23 and 24 depend from Claim 7; Claims 13 and 14 depend from Claim 12. These claims are also believed allowable over the references of record for the same reasons set forth with respect to their parent claims since each sets forth additional structural elements of Applicant's catheter assembly. Notice to that effect is requested.

In view of the foregoing remarks and amendments, Applicant respectfully submits that all of the claims in the application are in allowable form and respectfully solicits allowance of the same. If, however, any outstanding issues remain, Applicant urges the Patent Office to telephone Applicant's attorney so that the same may be resolved and the application expedited to issue. Applicant requests the Patent Office to indicate all claims as allowable and to pass the application to issue.

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Respectfully submitted,



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**CERTIFICATE OF MAILING**

I hereby certify that this **Amendment** is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on September \_\_, 2003.



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